

Serial No.: 10/624,583  
Attorney Docket No. 2C03.1-172  
CIBA Docket No.: SU/V-31277A/CVA

### **REMARKS**

Claims 12-18 are pending in the application. By the present Response and Amendment, no claims have been amended. No new matter is introduced. It is noted that two separate Office Action were issued on June 28, 2004 for this application. This Response and Amendment is responsive to both.

### **OBJECTIONS/COMMENTS**

The Examiner objected to the abstract since the abstract should be written as one paragraph with no indents and/or line spaces.

The abstract has been amended to one paragraph.

The Examiner stated that the title of the invention is not descriptive.

The title has been amended to match that of the parent application.

The Examiner reminded Applicants that the continuity data should be updated.

The CROSS REFERENCE TO RELATED APPLICATIONS has been amended to include the issued U.S. Patent No. assigned to the parent application.

### **DOUBLE PATENTING**

Claims 1-10 were rejected for double patenting.

This rejection is moot since Claims 1-10 were never presented in this case as they were cancelled in the Preliminary Amendment accompanying the application.

Serial No.: 10/624,583  
Attorney Docket No. 2C03.1-172  
CIBA Docket No.: SU/V-31277A/CVA

**35 U.S.C. 112, 2<sup>nd</sup> paragraph**

Claims 1-15 were rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner alleged that the recited steps (b) and (c) polymerizing and removing the porogen at temperatures above and below the cloud point of a composition is not indefinite [sic] because is does not give a reasonable guidance to one skilled in the art as to what temperature is meant, the cloud temperature of a porogen, as described on p. 8, lines 5-20. The Examiner alleges that the specification merely mentions the cloud points of porogens (Plurionics®) as being preferably between certain temperatures (p. 6, lines 4-6; p. 8, lines 5-20), however nothing is said about the "cloud point" of a composition or how to determine the "cloud point" of a composition.

Claims 1-11 are not present in this case. This rejection is moot toward those claims since Claims 1-11 were never presented in this case as they were cancelled in the Preliminary Amendment accompanying the application

Applicants respectfully traverse this rejection for Claims 12-15. The term "cloud point" is well known and understood by one of ordinary skill in the art and its application to any composition. A simple internet search (e.g., Google search of "cloud point") provides definitions of "cloud point" (e.g., <http://www.dow.com/surfactants/faq/#faq5>) as well as standard procedures (e.g., ASTM or cloud point testing equipment) for determining the cloud point of various compositions (e.g., surfactants or petroleum products). Further, Applicants would like to point Examiner's attention to page 12, lines 5-19. Applicants submit that the specification does define and teach the "cloud point" of a composition (formulation) and also provides reasonable guidance on how to determine the "cloud point" of a composition, in addition to being a term well known by one of ordinary skill in the art. Therefore, Applicants respectfully submit that Claims 12-15 meet the requirement of 35 U.S.C. § 112, and request withdrawal of this grounds of rejection.

Serial No.: 10/624,583  
Attorney Docket No. 2C03.1-172  
CIBA Docket No.: SU/V-31277A/CVA

Claim 11 was rejected as being indefinite since "undue experimentation" is involved to determine boundaries of protection.

Applicants respectfully point out that "undue experimentation" relates to enablement and "indefinite" relates to clarity of language. It is unclear if this rejection is meant to be a definiteness or enablement rejection. However, this rejection is moot whichever rejection is meant, as Claim 11 was never presented in this case (it was cancelled in the Preliminary Amendment accompanying the application).

### **35 U.S.C. 102**

Claims 1-3, 6-9, 11-15 were rejected under 35 U.S.C. 102(b) as being anticipated by Hennick et al. (U.S. 5,019,100).

Claims 1-3, 6-9, 11 are not present in this case. This rejection is moot toward those claims since Claims 1-3, 6-9, 11 were never presented in this case as they were cancelled in the Preliminary Amendment accompanying the application.

Claims 12-15 are addressed below by the remarks to the second June 28, 2004 Office Action rejection (i.e., 102/103 rejection of Claims 12-18).

### **35 U.S.C. 103**

Claims 4, 5 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hennick et al. (U.S. 5,019,100) in view of Kato et al. (U.S. 4,529,747).

Claims 4, 5 and 10 are not present in this case. This rejection is moot toward those claims since Claims 4, 5 and 10 were never presented in this case as they were cancelled in the Preliminary Amendment accompanying the application.

Serial No.: 10/624,583  
Attorney Docket No. 2C03.1-172  
CIBA Docket No.: SU/V-31277A/CVA

### **35 U.S.C. 102/103**

Claims 12-18 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 103(a) as obvious over Hennick et al. (U.S. 5,019,100).

Applicant respectfully traverses this rejection and requests reconsideration in view of the present remarks.

Hennick et al. disclose the use of a polymer network comprising a poly(meth)acrylate which is linked by means of oligomer chains which contain chemically bound ethylene oxide units as hydratable groups. The ethylene oxide units provide the "breathing" capability of the network. Other types of hydratable groups can be included in the network, "hydratable polymer segments." These segments allow additional hydration of the network. A preparation which yields the network of Hennick after curing contains a) prepolymer and, optionally, one or more of b) polymerizable (meth)acrylic derivative, c) N-vinylpyrrolidone, d) polymerizable antioxidant, e) agent for regulating viscosity, f) non-reactive solvent, g) additives such as fillers or coloring agents.

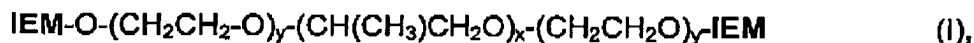
The final material of Hennick et al. is a polymer network. This network is poly(meth)acrylate linked with oligomer chains containing ethylene oxide. The ethylene oxide serves as hydratable groups.

The current claims are directed to a porous polymer, specifically a porous polymer molding. As discussed further below, the Hennink reference discloses different polymers and is not at all concerned with a process for the manufacture of porous polymers. The current polymer is not in a network linked by oligomer chains, but instead a porous polymer. The porogen used in manufacture of the composition leaves imprints (pores) when removed from the polymer and does not "link" the polymer.

Serial No.: 10/624,583  
 Attorney Docket No. 2C03.1-172  
 CIBA Docket No.: SU/V-31277A/CVA

Example 1 (col. 8) of Hennick et al. discloses a preparation which consists of PLURONIC PE 6400-IEM (hydroxypolyether), NVP (reactive solvent/hydratable group), water (solvent), QUANTACURE BTC and antioxidant. The preparation is introduced into a glass mold and irradiated to complete polymerization. The lens is then washed and dried.

U.S. 5,019,100 (Hennick et al.) is not concerned with porous polymers or the manufacture of porous polymers and does not use hydroxypolyethers devoid of polymerizable groups. Hennick et al. disclose "an intra-ocular lens comprising a poly(meth) acrylate linked by oligomer chains into a polymeric network, said oligomer chains containing chemically bound alkylene oxide units as hydratable groups" (Claim 1), i.e., the unsaturated alkylene oxide is copolymerized rather than merely included in the matrix. Accordingly, Hennick et al. are concerned with hydroxypolyethers which comprise covalently bound polymerizable groups, such as PLURONIC PE 6400-IEM (Example 1), which corresponds to formula



wherein IEM- designates the radical  $\text{CH}_2=\text{C}(\text{CH}_3)\text{-C(O)O-(CH}_2\text{)}_2\text{-NHC(O)-}$ . Therefore, "PLURONIC PE 6400-IEM", disclosed in Example 1 of Hennick et al. is "IEM-PEO-PPO-PEO-IEM" and is not "PEO-PPO-PEO". "IEM-PEO-PPO-PEO-IEM" is prepared from PEO-PPO-PEO, for example, by reaction with isocyanatoethyl methacrylate (IEM) in the presence of a tin salt catalyst (Hennick et al., Col. 5, lines 33-40). During the polymerization process according to Hennick et al., the PLURONIC PE 6400-IEM macromonomers (Col. 5, lines 27-47 and Example 1) are being crosslinked, thereby forming part of the polymeric network (Col. 3, lines 40 to 43). Therefore, in Hennick, the PLURONIC PE 6400-IEM macromonomers cannot be removed from the resulting polymer to form a porous polymer material.

Serial No.: 10/624,583  
Attorney Docket No. 2C03.1-172  
CIBA Docket No.: SU/V-31277A/CVA

Claim 16 of the present application is directed to: A hydratable porous polymer molding comprising

a composition of at least one polymerizable hydrophilic monomer or macromer, an inert porogen having an inverse temperature-dependent solubility which can be retained in the composition, and a solvent;

wherein the molding is formed by

providing said composition at a temperature below the cloud point temperature of the composition,

subjecting the composition to a polymerization reaction at a temperature around the cloud point temperature of the composition, and

removing the porogen from the resulting porous polymer at a temperature below the cloud point temperature of the composition.

Applicants submit that Hennink does not disclose nor motivate or suggest anything about a **porogen having an inverse temperature dependence solubility which can be retained in the composition**, about **curing of this composition around the cloud point temperature of the composition**, and about **removing of the porogen from the resulting porous polymer at a temperature below the cloud point temperature of the composition**.

Porogens are inert materials, devoid of polymerizable groups. After polymerization of a mixture of a polymerizable component and a porogen, leaching of the porogen may give rise to interstices throughout the formed polymer material (page 1, 3<sup>rd</sup> paragraph).

In contrast to Hennick et al., the present invention uses underivatized Pluronics® as example porogens, i.e., hydroxypolyethers of formula  $\text{HO}-(\text{CH}_2\text{CH}_2\text{O})_Y-(\text{CH}(\text{CH}_3)\text{CH}_2\text{O})_X-(\text{CH}_2\text{CH}_2\text{O})_Y\text{H}$  (abbreviated "PEO-PPO-PEO"), which are inert because they are devoid of ethylenically unsaturated groups. Underivatized Pluronics® do not take part in the

Serial No.: 10/624,583  
Attorney Docket No. 2C03.1-172  
CIBA Docket No.: SU/V-31277A/CVA

polymerization processes. As mentioned above, in the process of the present invention, Plurionics® are used as porogens, i.e., as inert materials which are subsequently being removed from the formed polymer material. Therefore, Applicants respectfully submit that the claims are not anticipated by Hennink, since Hennick et al. describe a structurally different polymer and that polymer is obtained by a different process and since the cited reference does not contain all of the elements of the claimed process. Applicants respectfully request withdrawal of the 35 U.S.C. §102(b) rejection.

The Applicable Law and the MPEP.

MPEP §706.02(j) requires:

"After indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office action:

...

(D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)." (emphasis added.)

Serial No.: 10/624,583  
Attorney Docket No. 2C03.1-172  
CIBA Docket No.: SU/V-31277A/CVA

Even in instances where prior art devices or references can be combined or modified to yield the claimed invention, and even though to modify the prior art would have been well within the ordinary skill of the art at the time the claimed invention was made, there must be some suggestion or motivation in the references, or some objective reason, to do so. Further, the proposed modification cannot change the principle of operation of the reference. MPEP §2143.01.

Applicants respectfully submit that the claims are not rendered obvious by Hennink, since the cited reference does not contain nor suggest or motivate all of the elements of the claimed composition or process by which it is made. Therefore, Applicants respectfully submit that, a *prima facie* case of obviousness cannot be established and request withdrawal of the 35 U.S.C. §103(a) rejection.

Claims 12-15 depend from Claim 16, and as Claim 16 is allowable, Claims 12-15 are also allowable. Accordingly, allowance of Claims 12-15 is respectfully requested.

Claim 17 of the present application is directed to: A hydratable porous polymer material comprising

a composition of at least one polymerizable hydrophilic monomer or macromer, an inert porogen having an inverse temperature-dependent solubility which can be retained in the composition, and a solvent;

wherein the composition is

polymerized at a temperature around the cloud point temperature of the composition, and

the porogen is removed from the resulting porous polymer at a temperature below the cloud point temperature of the composition.



Serial No.: 10/624,583  
Attorney Docket No. 2C03.1-172  
CIBA Docket No.: SU/V-31277A/CVA


For the same reasons as stated above for Claim 16, Claim 17 is neither anticipated nor obvious in view of the recited Hennick et al. reference. Applicants respectfully request withdrawal of the 35 U.S.C. §102(b)/103(a) rejection.

Claim 18 depends from Claim 17, and as Claim 17 is allowable, Claim 18 is also allowable. Accordingly, allowance of Claim 18 is respectfully requested.

### **CONCLUSION**

In view of the remarks submitted herein and the above comments, it is believed that all grounds of rejection are overcome and that the application has now been placed in full condition for allowance. Accordingly, Applicant earnestly solicits early and favorable action. Should there be any further questions or reservations, the Examiner is urged to telephone Applicant's undersigned attorney at (770) 984-2300.

Respectfully submitted,

  
\_\_\_\_\_  
Patricia L. Ades  
Reg. No. 44,496

Customer No.: 23506  
GARDNER GROFF, P.C.  
Paper Mill Village, Building 23  
600 Village Trace, Suite 300  
Marietta, GA 30067  
Tel: 770/984-2300  
Fax: 770/984-0098